PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 041346WO CS/gn	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/EP2004/006733	International filing date *(day/month/year)* 22.06.2004	Priority date *(day/month/year)* 23.06.2003
International Patent Classification (IPC) or national classification and IPC A61K39/35, A61K38/01		
Applicant BIOTECH TOOLS SA et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
05.04.2005	02.11.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Ludwig, G Telephone No. +49 89 2399-8698

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/006733

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-13 as originally filed

Claims, Numbers

1-14 as originally filed

Drawings, Sheets

1/7-7/7 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/006733

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-10, 11-14
	No:	Claims	11
Inventive step (IS)	Yes:	Claims	1-10, 11-14
	No:	Claims	11
Industrial applicability (IA)	Yes:	Claims	1-14 (cf. separate sheet)
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Item V:

D1: US-B1-6312711
D2: Biochemical And Biophysical Research Communications (1996), 223(3), 492-495
D3: Journal Of Food Science (1988), 54(4), 1037-1039

1. *Oral* desensitization is known from document D1 disclosing pharmaceutical or food compositions for treating pathologies related to graft versus host, allergic or autoimmune reactions. In D1 pepsin was used for digestion of the antigenic structures, to obtain the respective epitopes.

   Document D2 discloses preparation of a haptenic peptide mixture (HPM) for the treatment of wheat allergy by digestion with **chymotrypsin**.

   Document D3 investigates the efficiency of different peptidases in the production of allergy reducing epitopes from alpha-lactalbumin and ß-lactoglobulin to be used in infant milk formula (containing potentially allergic cow milk allergenic proteins in infant food for children where mother's milk cannot be provided). **Chymotrypsin** alone was as effective as its combination with trypsin, whereas the combination of **chymotrypsin** with pepsin was most effective.

2. Claim 1 refers, in principle, to a pharmaceutical composition **for sublingual, buccal or enteric administration** comprising an antigenic structure hydrolyzed by chymotrypsinogen which induces graft rejection, allergic reaction or autoimmune disease.

   Such formulations which need to be in a special galenic form to be suitable for sublingual, buccal or enteric administration are not disclosed nor suggested by documents D1-D3.

3. Claim 11 claims, in essence, a composition comprising a substance obtainable by

hydrolysis with chymotrypsinogen, said substance being an antigenic structure which induces graft rejectin, alllergic reaction or autoimmune disease.

Such compositions are already known from documents D1-D3.

4. For the assessment of the present claims 8-9 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Item VIII.

5. The description on page 4, para 3 is not in line with the claims ("..hydrolysis can also be performed with any other protease ...").